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Abstract

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PI Title: ASSOCIATE PROFESSOR

Project Title: MANAGEMENT OF SLEEP-ACTIVITY DISRUPTION IN ALZHEIMERS

Abstract: *The purpose of these thre phased randomized clinical trial is to test the effectiveness of bright light therapy and melatonin in reducing sleep- activity (circadian) disruption in institutionalized Alzheimer's disease (AD) patients. Disturbances in sleep-activity rhythm are prominent and disabling symptoms in AD. Nighttime sleep is severely fragmented and daytime activity is disrupted by multiple napping episodes and afternoon delirium (sundowning). AD-related neurological damage, institutionalization, and decreased in external zeitgebers that influence circadian rhythms (e.g., bright light) probably all contribute to the etiology. Medical treatment has proven only minimally effective and is associated with numerous and serious side effects. Development and testing of innovative strategies such as properly time bright light exposure and exogenous administration of melatonin (a neurohormone produced by the pineal gland during darkness) are needed. In Phase I of this study, the following hypothesis will be tested: subjects exposed to bright outdoor light (greater than or equal to 5000 lux) for one hour per day (9-10AM) for 10 weeks will exhibit a decreased number of nighttime awakenings, decreased total wake time after sleep onset, and decreased problematic nighttime behaviors compared to control subjects. In Phase II, the hypothesis that morning (9-10AM) bright light (greater than or equal to 5000 lux) exposure is more effective than afternoon (4-5PM) bright light (greater than or equal to 5000 lux) in improving the outcome measures will be tested. In Phase III, a bedtime dose of melatonin will be added to the intervention found to be most effective in Phase II and the addition effect of melatonin on the outcome variables tested. Subjects (n=64 in each phase) meeting the NINCDS-ADRDA AD diagnostic criteria will be recruited from the second largest skilled*

nursing facility in the state. Number of awakenings and total wake time after sleep onset will be assessed using the Advanced Mini Motionlogger (Actigraph)l problematic nighttime behaviors will be assessed using the Neuropsychiatric Inventory: Nursing Home. To test the hypothesis, repeated measures analysis of co-variance (2x5 factorial design, two groups, 5 times) using the baseline as a covariate will be used on each outcome measure. Differences will be determined in the main effects between groups, main effects within groups over time, and the interaction between group and time. Post-hoc contrasts (Tukey) will be performed as needed.

Thesaurus Terms:
Alzheimer's disease, circadian rhythm, hormone therapy, human therapy evaluation, melatonin, phototherapy, sleep disorder
clinical trial, gender difference, sleep, wakefulness
clinical research, human subject, neuropsychological test, placebo

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